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THIS IS A COMMUNICATION FROM THE EXAMINING DIVISION OF THE
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice re Patent Drawing, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 1-12 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-12 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-12 are rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Bartl in view of Terminiello in further view of either Hawkins or Tripodi.

Bartl (5,059,525) entitled "Dry Reagent for Blood Coagulation Tests" teaches in the claims a test strip for carrying out a Quick Test, a known prothrombin time assay, where the test strip contains thromboplastin, in claim 11 a phospholipid.

The claims differ from Bartl in that they include additional agents.

Terminiello (4,774,192) entitled "A Dry Reagent Delivery System with Membrane Having Porosity Gradient" teaches in claim 1 a dry chemistry reagent system for analysis of fluid samples having a membrane where the membrane contains a reagent and an indicator and further contains a conditioning agent. In column 13 lines 31-43 flow control agents are shown. In column 16 last word bridging to column 17 first paragraph, surfactant is shown.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the flow control agents or surfactant of Terminiello in the test strip of Bartl because one would have a high expectation of success by employing known agents for their known functions. Note that buffers and surfactants are well known in the test strip art.

The claims further differ from the above references in that they specify the thromboplastin is purified and present claim 3 specifies it is relipidated recombinant tissue factor.

Hawkins (Clinical Hemostasis Review) entitled "Prothrombin Time Reagents Prepared Using Recombinant Human Tissue Factor Produced in E. Coli" teaches in column 2 first full paragraph, Recombinant human tissue factor lipidated with phospholipids has been used to develop a PT reagent with advantages of sensitivity and rapid response. On the second page column 2 second full paragraph the reagent is reconstituted. Note on page 3 lines 30-

34 of the present specification synthetic recombinant thromboplastin consists of a complex formed by purified recombinant tissue factor protein and a purified artificial lipid.

Tripodi (Thrombosis and Haemostasis) entitled "Recombinant Tissue Factor as Substitute for Conventional Thromboplastin in the Prothrombin Time Test" teaches in the Summary in column 1, Relipidated recombinant tissue factor possesses the necessary requisites of sensitivity, diagnostic accuracy and reproducibility which make it a suitable candidate for PT diagnosing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the recombinant thromboplastin shown by Hawkins or Tripodi for conventional extracted thromboplastin in the test strip of Bartl because both Hawkins and Tripodi state a direct comparison between conventional extracted thromboplastin and recombinant thromboplastin shows preferred advantages of recombinant thromboplastin.

Furthermore, the 35 USC § 103 statute does not require that the prior art identically disclose or describe Applicants invention but rather that no patent should be obtained if the subject matter as a whole would have been obvious to persons having ordinary skill in this art at the time this invention was made.

Claims 1-12 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited in accordance to specific embodiments set forth in the specification. See M.P.E.P. §§ 706.03(n) and 706.03(z).

In claim 1 and all occurrences the terms "coagulation neutral agents," in claim 4 and all occurrences "proteins, water soluble polymers and surfactants" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such substances would work in the instant invention.

"Proteins, water soluble polymers and surfactants" reads on many substances such as catalase which will interfere with the determination.

On page 13 first full paragraph of the present specification a number of "coagulation neutral agents" are shown but on page 15 of the specification BSA and hydrolyzed polyvinyl alcohol only are enabled.

Also, due to the unpredictability of the chemical and biotechnological arts the extension of the substances provided in the working examples of the specification to other proteins, polymers and surfactants is highly uncertain. There is no direction to determine the optimum combination and selection of compounds.

Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-4 the preamble of "a test article" is queried as it is unclear if the article is tested. In claim 1 and all occurrences "a solid phase" refers to the phase of an object, but does not specify what the object is, only that the object is not a liquid or gas. In claim 5 line 5 "intended" renders the claim indefinite because the agents may or may not perform as intended. In claim 5 penultimate line "faced" is queried. In claim 9 last line "with plasma sample" is queried regarding antecedent basis and may be intended to be "the sample." The preamble of claim 12 is "the method" lacks antecedent basis where the preamble of claim 9 from which it depends is "an improved prothrombin time assay."

On page 5 line 22 of the specification copending serial numbers 07/874,667 and 08/003,791 are incorporated by reference. Note that 07/874,667 has been abandoned and 08/003,791 is a non-analogous art. Pending application 08/196,816 may be intended.

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing

application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157; *In re Hawkins*, 486 F.2d 579, 179 USPQ 163; *In re Hawkins*, 486 F.2d 577, 179 USPQ 167.

The Abstract of the Disclosure is objected to because of legal phraseology such as comprise and preferred embodiment. Correction is required. See M.P.E.P. § 608.01(b).

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The date of the A5 reference cited on PTO-1449 is not included and a complete citation of the publication would be appreciated.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon: Barrow (5,254,350) teaches a method of preparing thromboplastin extract and Hawkins (5,270,451) teaches an extraction method for preparing thromboplastin reagents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Wityshyn, can be reached on

(703) 308-4743. The fax phone number for this Group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RG

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